

SEP 13 2005

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Endoscopic Technologies, Inc.

ESTECH Cobra System Model Amendments  
Premarket Notification

**SECTION 1 – GENERAL DESCRIPTION**  
**510(k) Notification Information Collection**

Sponsor

Endoscopic Technologies, Inc.; d/b/a Estech

K 051749

Person Responsible for File

Art Bertolero  
Chief Executive Officer  
Estech Technologies

Device Trade Name

Estech Cobra Surgical System™

Accessories presented in this premarket notification:

Estech Cobra Adhere XL Surgical System  
Estech Cobra Surgical Probe  
Estech Cobra Bipolar Recording Electrode

Common Name

Electrosurgical Probes and accessories

Classification Name

Class II, Electrosurgical cutting and coagulation device and accessories (21 CFR 878.4400);

Product Code

GEI

Establishment Registration Number

2953686

Address of Manufacturing Facility and Sterilization Site:

Manufacturing Facility

4135 Blackhawk Plaza Circle  
Suite 150  
Danville, CA 94506  
Tel: 925-648-3500  
Contact: Art Bertolero  
Establishment Registration:  
2953686

Sterilization Site

Sterigenics  
5725 W. Harold Gatty Dr.  
Salt Lake City, UT 84116  
Tel: 801-328-9901  
Fax: 801-328-9002  
Establishment Registration:  
1721676

**SECTION 2 – 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS****Device Information:**

Category	Comments
Sponsor:	Estech 4135 Blackhawk Plaza Circle . Suite 150 Danville, CA 94506 Tel: 925-648-3500
Correspondent:	Craig Coombs Coombs Medical Device Consulting 1193 Sherman Street Alameda, CA 94501
Contact Information:	Tel: 510-337-0140 Fax: 510-337-0416
Device Common Name:	Electrosurgical Probe
Device Proprietary Name:	Estech Cobra Surgical System™
Device Classification:	21 CFR 878.4400

**Predicate Device Information:**

Predicate Devices:	Electrosurgical Probe (K981981) Cobra Adhere Surgical System (K041599) Detect Mapping and Pacing Tool (K040812)
Predicate Device Manufacturers:	Boston Scientific Corporation Endoscopic Technologies Medtronic
Predicate Device Common Name:	Electrosurgical Probe
Predicate Device Classification:	21 CFR 878.4400
Predicate Device Classification Number:	Class II

**b. Date Summary Prepared**

July 22, 2005

**c. Description of Device**

The Estech Cobra Surgical System is a family of devices including RF Ablation Probes, with either a malleable or flexible shafts, used in conjunction with the Cobra Electrosurgical Unit (ESU) and other accessories, including the Estech Cobra Bipolar Recording Electrode. The System is intended for use by surgeons for the coagulation of cardiac and soft tissues during open surgical procedures.

**d. Intended Use**

The intended use for the Estech Cobra Surgical System is as follows:

*The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during*

*general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.*

**e. Comparison to Predicate Device**

The XL version of the Estech Cobra Surgical System is substantially equivalent in intended use, technology, design and materials to the predicate device. The XL version has up to seventeen electrodes on the ablation probe. The original premarket notification device had an upper limit of seven electrodes. The Stabilizers differ in size and handle configuration. The XL version has an Introducer to facilitate the placement of the System.

The Estech Cobra Surgical Probe is substantially equivalent in intended use, technology, design and materials to the predicate system. The Cobra Surgical Probe does not have the capability for a cooling stream of water to be run through the shaft and it does not interface with a Stabilizer. This version of the Cobra Surgical Probe is identical to the Boston Scientific Electrosurgical Probe.

The Estech Cobra Bipolar Recording Electrode is substantially equivalent to the surgical intended use, sensing and pacing characteristics of the predicate device. Both are hand-held devices that are intended to be used only in an open surgical field. They are not implantable.

**f. Summary of Supporting Data**

No biocompatibility data is necessary since the materials in the modified ablation probes (XL and Surgical Probe) are identical to those described in the predicate 510(k)s. The materials of the Recording Electrode are identical to those in the ablation probes.

Preclinical performance data is supplied to demonstrate that the XL version of the cooled Estech Cobra Adhere Ablation Probe met the same pertinent specifications as the predicate version.

No performance data is necessary for the Estech Cobra Surgical Probe since it is identical in design, materials and manufacture to the predicate device.

Preclinical performance data is supplied to demonstrate that the Estech Cobra Bipolar Recording Electrode operates as intended.

Additionally, Estech certifies that the accessories are in compliance with the pertinent sections of the FDA consensus standard, *AAMI / ANSI HF-18: Electrosurgical devices*.



FEB 21 2008

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Estech, Inc.  
c/o Mr. Craig Coombs  
Coombs Medical Device Consulting  
1193 Sherman Street  
Alameda, CA 94501

Re: K051749  
Trade/Device Name: Estech Cobra Surgical System™  
Regulation Number: 21 CFR 878.4400  
Regulation Name: Electrosurgical cutting and coagulation device and accessories  
Regulatory Class: II (two)  
Product Code: OCL, GEL  
Dated: June 27, 2005  
Received: July 7, 2005

Dear Mr. Coombs:

This letter corrects our substantially equivalent letter of September 13, 2005.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 - Mr. Craig Coombs

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman".

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

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Indications for Use510(k) Number (if known): K051749Device Name: Estech Cobra Surgical System™

## Indications For Use:

The Estech Cobra Surgical System is intended for the coagulation of cardiac tissue using radiofrequency (RF) energy during cardiac surgery. The System can be used during general surgery to coagulate soft tissues. The System may also be used to coagulate blood and soft tissue to produce hemostasis.

Prescription Use X

AND/OR

Over-The-Counter Use

(Part 21 CFR 801 Subpart D)

(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER  
PAGE IF NEEDED)Barbara P. Mehl

(Division Sign-Off)

Division of General, Restorative,  
and Neurological Devices

Concurrence of CDRH, Office of Device Evaluation (ODE)

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CONFIDENTIAL

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